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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/763,813	02/26/2001	David Edwin Thurston	65435-9001	3683

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EXAMINER

WRIGHT, SONYA N

ART UNIT PAPER NUMBER

1626

DATE MAILED: 02/28/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/763,813

Applicant(s)

THURSTON ET AL.

Examiner

Sonya Wright

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17-19 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 18 is/are rejected.
- 7) ☒ Claim(s) 17 and 19 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

This is a response to Applicant's remarks filed 12-10-02. Claims 1-26 are pending in this application.

The objection to claims 17-19 for containing non-elected subject matter has been maintained for the reasons of record. The rejections under 35 U.S.C. 102 and 103 have been withdrawn. The rejection under 35 U.S.C. 112 second paragraph has been overcome by Applicant's amendment.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 18 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. For rejections under 35 U.S.C. 112, first paragraph, the following factors must be considered (In re Wands, 8 USPQ2d 1400, 1404 (CAFC, 1988)):

- 1) Nature of invention.
- 2) State of prior art.
- 3) Level of ordinary skill in the art.
- 4) Level of predictability in the art
- 5) Amount of direction and guidance provided by the inventor.

6) Existence of working examples.

7) Breadth of claims.

8) Quantity of experimentation needed to make or use the invention based on the content of the disclosure.

Claim 18 is directed to "a method of therapy". The specification does not reasonably provide enablement for the instantly claimed method of use.

The specification does not enable any person skilled in the art to which it pertains to use the invention commensurate in scope with this claim. In particular, the specification fails to enable the skilled artisan to practice the invention without undue experimentation. The term therapy is broad and the prior art does not indicate that the instant compound is useful in all forms of therapy. Applicant gives limited guidance regarding how the instant compound is useful in therapy. Applicant has not given evidence that their compound is useful in all forms of therapy. On page 7, lines 15-18, Applicant discloses that the instant compound may be useful in treating gene-based diseases, including neoplastic diseases and, for example Alzheimer's disease, and bacterial, parasitic and viral infections. Applicant gives one in vitro cytotoxicity assay, on page 32, however, this does not support that the instant compound is useful in all forms of "therapy". The level of ordinary skill in the art is high. The skilled artisan would have a numerous amount of experiments to perform in order to identify which disorders the instant compound is useful in treating. Therefore undue experimentation would be required to use the instant compound in therapy as claimed. This rejection can be overcome by Applicant limiting claim 18 to the disorders that are supported in the

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specification as being treatable with the instant compound, e.g. the disorders listed on page 7, lines 15-18: gene-based diseases, Alzheimer's disease, and bacterial, parasitic and viral infections.

Claim Objections

Claims 17-19 are objected to as containing non-elected subject matter. In the Office Action mailed 9-10-02, a generic concept was set forth which did not include a limitation of the variable "R". Upon further consideration, the "R" variable has been limited. It is requested that Applicant limit the claims to the generic concept in the Office Action mailed 9-10-02, and that Applicant include the following limitation of the variable "R": R is a lower alkyl group having 1 to 10 carbon atoms, or an aralkyl group of up to 12 carbon atoms, whereof the alkyl group optionally contains one or more carbon-carbon double or triple bonds, which may form part of a conjugated system; and is optionally substituted by one or more halo, hydroxy amino, or nitro groups, and optionally contains one or more hetero atoms, which may form part of, or be, a functional group.

Response to Arguments

Applicant's arguments filed 12-10-02 have been fully considered and are persuasive with respect to the rejections under 35 U.S.C. 102 and 103, therefore, these rejections have been withdrawn. Applicant's arguments are not persuasive with respect to the objection to claims 17-19 for containing non-elected subject matter. Applicant's amendment to claim 18 obviated the rejection under 35 U.S.C. 112 second paragraph,

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however amended claim 18 has been rejected under 35 U.S.C. 112 first paragraph (supra).

Regarding the objection to claims for containing non-elected subject matter, Applicant submits that the restriction is traversed for the reasons of record.

However, the withdrawn subject matter of claims 17-19 is properly restricted as said subject matter differs in structure and element from the elected subject matter so as to be patentably distinct therefrom, i.e. a reference which anticipated the elected subject matter would not even render obvious the withdrawn subject matter and fields of search are not co-extensive.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sonya Wright, whose telephone number is (703) 308-4539. The examiner can normally be reached on Monday-Friday from 8:00 AM - 5:30 PM.

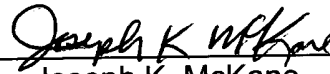
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Joseph K. McKane, can be reached at (703) 308-4537. The Unofficial fax phone number for this Group is (703) 308-7922. The Official fax phone numbers for this Group are (703) 308-4556 or 305-3592.

When filing a FAX in Technology Center 1600, please indicate in the Header (upper right) "Official" for papers that are to be entered into the file, and "Unofficial" for draft documents and other communications with the PTO that are not for entry into the file of the application. This will expedite processing of your papers.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [joseph.mckane@uspto.gov]. All Internet e-mail communications will be made of record in the application file. PTO employees will not communicate with applicant via Internet e-mail where sensitive data will be exchanged or where there exists a possibility that sensitive data could be identified unless there is of record an express waiver of the confidentiality requirements under 35 U.S.C. 122 by the applicant. See the Interim Internet Usage Policy published by the Patent and Trademark Office Official Gazette on February 25, 1997 at 1195 OG 89.

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Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-1235.

A handwritten signature in cursive script, reading "Joseph K. McKane", is written over a horizontal line.

Joseph K. McKane

Supervisory Patent Examiner

Group 1600

Sonya Wright

February 26, 2003